K002702

OCT 2 6 2000

510(k) Summary of Safety and Effectiveness

Trade Name:	Neurotology Drape
Common Name:	Sterile Surgical Drape
Classification Name:	Drape, Surgical (§ 878.4370)

Official Contact: Greg Sredin
Regulatory Affairs Specialist
Smith & Nephew, Inc.
ENT Division
2925 Appling Road
Bartlett, TN 38133

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Date Prepared: August 29, 2000.

Intended Use

The Neurotology Drape is intended to be used as a protective patient covering during otological surgical procedures. The primary purpose of the drape is to isolate a site of surgical incision from microbial or other contamination.

Materials

The Neurotology Drape will be constructed with the following materials:

1. A non-woven fabric designed for fluid repellency and softness that is a blend of natural wood pulp fibers with polyester that are bound together by a pure synthetic acrylic polymer binder treated online for liquid barrier.
2. A poly/foam laminate comprised of polyethylene film and polyurethane foam.
3. The adhesive used in the drape is an unsupported non-sensitizing acrylic pressure sensitive transfer film.
4. The polyurethane film used in the drape as the ingress for a speculum holder is a polyester polyurethane formulated for excellent physicals, vacuum forming, and sealability. This material is to be located at the edge of the operating table and will not be in contact with the patient.
5. The fluid collection bag, port, and collection bag surround are manufactured of polyethylene; a material long used by medical device manufacturers.

Design Features

The Neurotology Drape is intended for patients undergoing Otological procedures. It uses non-woven and film materials as a protective patient covering during surgical procedures. These barrier materials are essentially impervious to fluid transfer, thus function to isolate the operative site from the surrounding area. The drape features tape adhesive to temporarily bind the drape to the operative site. It features a fluid collection pouch for the collection of operative wound solid and liquid effluents. It will also feature a perforated elastic window to allow the ingress of a speculum holder into the operating field. The Neurotology Drape will be subjected to a sterilizing dose of ethylene oxide (EO) sufficient to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

The primary difference between the DEKA Medical Surgical Drapes and the Smith & Nephew Neurotological Drape is the method of sterilization. The DEKA Medical Surgical Drapes are gamma irradiation sterilized whereas the Smith & Nephew Neurotological Drape is Ethylene Oxide sterilized. However, sterility is assured by either method.

Differences between the Smith & Nephew, Inc., ENT Division Neurotological Drape and the predicate device should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2000

Mr. Greg Sredin
Regulatory Affairs Specialist
Smith & Nephew, Incorporated
2925 Appling Road
Bartlett, Tennessee 38133

Re: K002702
Trade Name: Neurotology Drape, Blue
Regulatory Class: II
Product Code: KKX
Dated: October 6, 2000
Received: October 10, 2000

Dear Mr. Sredin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

this letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002702
Device Name: Neurotology Drape, BLUE

Indications For Use:

The Neurotology Drape is intended to be used as a protective patient covering during otological surgical procedures. The primary purpose of the drape is to isolate a site of surgical incision from microbial or other contamination.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

SKB for Chn
(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K002702